

REMARKS

Claims 1-46 are pending in the Application. Claims 1, 2, 4-15, 17-20, and 22-46 stand rejected in the Office Action. Claims 3, 16 and 21 are objected to in the Office Action as depending from a rejected claim, but contain allowable subject matter. Applicants offer new claims 47-56 with this reply. Upon entry of the Amendment, claims 1-56 remain pending.

Support for new claims 47-56 is found in the original specification as filed, including the claims. For example, the subject matter of claims 47-56 parallels in large part the subject matter of claims 1-14 currently in the case. Claims 47-56 contain the additional limitation that the water soluble polymer of the coating is also alcohol soluble. Support for this limitation is found in the specification, for example at paragraph 10 and paragraph 20. The specification teaches that the coating materials are first dissolved in alcohol to form a coating solution. The coating solution is then sprayed onto the tablet cores. The specification at paragraph 20 further describes the conditions of spraying. Applicant respectfully submit that the specification is sufficient to show that Applicants were in possession of the invention of claims 47-56 at the time of filing. Applicants respectfully request entry of the Amendments.

Personal Interview with Examiner Spear

Applicant would like to thank Examiner Spear for the courtesies shown to Applicant's representative in a personal interview on Tuesday, August 5, 2003. In the interview, the pending claims were discussed, and especially the enablement rejection related to the limitation "water soluble polymer". Although agreement was not reached as to allowable subject matter, the Examiner expressed his willingness to consider arguments in favor of the enablement of such a limitation.

Rejection Under 35 U.S.C. § 112

Claims 1, 2, 4-15, 17-20, and 22-46 stand rejected under 35 U.S.C. §112. The Office Action states that the specification, while being enabling for polyvinylpyrrolidone, does not reasonably provide enablement for a “water soluble polymer”. The Examiner states the specification does not enable a person skilled in the art to make and use the invention commensurate in scope with the claims. On the basis of the discussion below, Applicant respectfully submits that a person of skill in the art is enabled to use a water soluble polymer in the invention of claims 1-46, and in new claims 47-56. Accordingly, Applicant respectfully traverses the rejection and requests reconsideration.

The key factual inquiry under §112, first paragraph, is whether the specification enables a person skilled in the art to make and use the invention without “undue experimentation”. The determination that “undue experimentation” would have been needed to make and use the claimed invention is not a single simple factual determination, but is a conclusion to be reached by weighing a variety of factual considerations. *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988). In *In re Wands*, the Federal Circuit listed a non-exclusive list of factors that may be considered when determining whether a disclosure meets the enablement requirements of 35 U.S.C. §112. These factors include but are not limited to:

- a) the breadth of the claims,
- b) the nature of the invention,
- c) the state of the prior art,
- d) the level of one of ordinary skill,
- e) the level of predictability in the art,

f) the amount of direction provided by the inventor,
g) the existence of working examples, and
h) the quantity of experimentation needed to make or use the invention based on the content of the disclosure.

Applicants believe an analysis of the above factors demonstrates that the limitation "water soluble polymer" in the rejected claims is in fact enabled to one of skill in the art. Relevant factors are discussed below in turn.

a) Breadth of the Claims

Although the rejected claims are all drawn to tablets that contain water soluble polymers as part of their coatings, the overall scope of the claims is in fact relatively limited. All of the claims require a core containing a specified active ingredient, metformin. By use of the term water soluble polymer, Applicants are not attempting to broaden the claims beyond what is described in the specification. Because Applicants have in fact enabled the invention by giving an example (PVP) of a water soluble polymer, Applicants believe that this factor favors a conclusion that the claims are enabled.

b) Nature of the Invention

The nature of the invention is a release composition in the form of a tablet that contains an active ingredient, metformin, in the core. The metformin in the core supplies the mode of action for the extended release tablet, while the water soluble polymer of the coating contributes to the dissolution profile of the tablet. The use of water soluble polymers in such

compositions is known. Applicants believe that the factual conclusions relative to this factor also favor a finding of enablement of the invention.

c) State of the Prior Art

The state of the prior art is illustrated in part by the attached U.S. Patent 5,505,962 to Elan Corporation, Inc., which was discussed with the Examiner at the personal interview. Attention is respectfully drawn to column 4, beginning at line 35, where the patent discusses preferred materials for the “permeable component” of the membrane. The “permeable component” of the membrane corresponds generally to the water soluble polymer of the coating of the current invention. In the patent, preferred materials for such a component are listed as polyvinyl alcohol, polyvinylpyrrolidone, polymers of acrylic and methacrylic acid and esters thereof, such as EUDRAGIT RL™, and hydroxypropylmethyl cellulose. On the basis of the above, Applicants believe that this factor also favors a conclusion that a limitation of water soluble polymer is enabled in the current specification.

d) Level of Ordinary Skill

The level of ordinary skill in the pharmaceutical area and in extended release tablets is generally considered as being quite high. As a rule, the person of ordinary skill has a college degree, and more likely an advanced degree such as a Doctorate. A person of such high skill would be quite aware of what polymers are considered to be water soluble. For example, not only would the person of skill in the art be aware of prior art patents, such as U.S. 5,505,962 discussed above, he would also be familiar with treatises, such as the attached pages from Volume 17 of the Encyclopedia of Polymer Science and Engineering. Attention is respectfully

drawn to Figure 2 on page 732 of the Encyclopedia. Figure 2 shows a variety of functional groups that impart water solubility to a polymer. Other pages of the encyclopedia that are not attached give specific examples of water soluble polymers, including polysaccharides, hydroxyethyl cellulose, hydroxypropyl cellulose, carboxymethyl cellulose, nonionic polymers such as polyacrylamide, polyacrylic acids, polyethylene oxide, polyvinyl alcohol, polyvinylpyrrolidone, and others. Applicant believes that this factor also favors a conclusion that the term “water soluble polymer” in the current rejected claims is enabled to a person of skill in the art.

e) Level of Predictability in the Art

Although extended release formulations in general are not necessarily predictable, it is predictable which polymers would be soluble in water based on the knowledge of a person skilled in the art as discussed above. Accordingly, Applicants respectfully submit that this factor also favors a conclusion that water soluble polymers are enabled in the specification.

f) The Amount of Direction Provided by the Inventor

Attention is respectfully drawn to the specification on page 5. There the inventor discusses the use of the water soluble and water insoluble polymers to produce tablets having desired extended release profiles. The inventor instructs that if a more extended release is desired then a relatively greater amount of the insoluble polymer should be used in the coating. Implicitly, the inventor thus teaches that the rate of extended release can be altered by changing the amount of water soluble polymers. More water soluble polymers should be used if a faster release is desired and less water soluble polymer should be used if a slower release rate is

desired. This teaching of the inventor, together with the knowledge of the person of skill in the art of exactly which polymers are expected to be water soluble, lends support to the conclusion that the specification is enabling as to water soluble polymers.

g) The Existence of Working Examples

The inventor gives several working examples of water soluble polymers in the specification. Although, as noted by the Examiner, the working examples are drawn to polyvinylpyrrolidone as the water soluble polymer, Applicant respectfully submits in light of the above discussion that the person of skill in the art would be readily able to practice the invention with other water soluble polymers. Applicants believe that this factor too favors the conclusion that the water soluble polymers of the claims are enabled.

h) The Quantity of Experimentation Needed to Make or Use the Invention Based on the Content of the Disclosure

In light of the discussion of factors a) through g), Applicants respectfully submit that this factor also favors a conclusion that the water soluble polymer of the claim is enabled to a person of skill in the art. Because the person of skill in the art has a high level of training, perhaps at the Ph.D. level, because the prior art patents and treatises teach numerous examples of water soluble polymers for use in pharmaceutical applications, and because the inventor has described water soluble polymers for use in his invention by way of working examples and by way of instructions for use, Applicants respectfully submit that a person of skill in the art could carry out the claimed invention without undue experimentation.

Applicant has addressed the rejection of Claims 1, 2, 4-15, 17-20, and 22-46 in light of the *Wands* factors. On the basis of the above, Applicant respectfully submits that the

rejected claims are in fact enabled to one of skill in the art. Accordingly, Applicant respectfully requests that the rejections be withdrawn.

New Claims 47-56

New claims 47-56 are drawn to extended release tablets where the coating contains a polymer soluble both in water and in alcohol. Support for the new claims is discussed above. Applicant respectfully submits that the subject matter of claims 47-56 is enabled to a person of skill in the art for the same reasons as discussed above with respect to claims 1-46.

Accordingly, Applicant respectfully submits that Claims 47 through 56 comply with the requirements of 35 U.S.C. §112, first paragraph.

CONCLUSION

For the reasons discussed above, Applicants believes that claims 1-56 are in an allowable state and request an early notice of such allowance. The Examiner is invited to telephone the undersigned if that would be helpful to resolving any issue.

Respectfully submitted,

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